

<b>Notice of Allowability</b>	<b>Application No.</b>	<b>Applicant(s)</b>	
	09/589,255	LINK ET AL.	
	<b>Examiner</b>	<b>Art Unit</b>	
	Anne Marie S. Wehbe	1632	

**-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address--**

All claims being allowable, PROSECUTION ON THE MERITS IS (OR REMAINS) CLOSED in this application. If not included herewith (or previously mailed), a Notice of Allowance (PTOL-85) or other appropriate communication will be mailed in due course. **THIS NOTICE OF ALLOWABILITY IS NOT A GRANT OF PATENT RIGHTS.** This application is subject to withdrawal from issue at the initiative of the Office or upon petition by the applicant. See 37 CFR 1.313 and MPEP 1308.

1. ☒ This communication is responsive to the amendment filed on 3/11/05.
2. ☒ The allowed claim(s) is/are 19-21, 24-26, 31 and 32.
3. ☒ The drawings filed on 07 June 2000 are accepted by the Examiner.
4. ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
  - a) ☐ All   b) ☐ Some\*   c) ☐ None   of the:
    1. ☐ Certified copies of the priority documents have been received.
    2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
    3. ☐ Copies of the certified copies of the priority documents have been received in this national stage application from the International Bureau (PCT Rule 17.2(a)).
  - \* Certified copies not received: \_\_\_\_\_.

Applicant has THREE MONTHS FROM THE "MAILING DATE" of this communication to file a reply complying with the requirements noted below. Failure to timely comply will result in ABANDONMENT of this application.  
**THIS THREE-MONTH PERIOD IS NOT EXTENDABLE.**

5. ☐ A SUBSTITUTE OATH OR DECLARATION must be submitted. Note the attached EXAMINER'S AMENDMENT or NOTICE OF INFORMAL PATENT APPLICATION (PTO-152) which gives reason(s) why the oath or declaration is deficient.
6. ☐ CORRECTED DRAWINGS ( as "replacement sheets" ) must be submitted.
  - (a) ☐ including changes required by the Notice of Draftsperson's Patent Drawing Review ( PTO-948 ) attached
    - 1) ☐ hereto or 2) ☐ to Paper No./Mail Date \_\_\_\_\_.
  - (b) ☐ including changes required by the attached Examiner's Amendment / Comment or in the Office action of Paper No./Mail Date \_\_\_\_\_.

**Identifying indicia such as the application number (see 37 CFR 1.84(c)) should be written on the drawings in the front (not the back) of each sheet. Replacement sheet(s) should be labeled as such in the header according to 37 CFR 1.121(d).**
7. ☐ DEPOSIT OF and/or INFORMATION about the deposit of BIOLOGICAL MATERIAL must be submitted. Note the attached Examiner's comment regarding REQUIREMENT FOR THE DEPOSIT OF BIOLOGICAL MATERIAL.

**Attachment(s)**

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|---|--|
| <ol style="list-style-type: none"> <li>1. <input type="checkbox"/> Notice of References Cited (PTO-892)</li> <li>2. <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)</li> <li>3. <input type="checkbox"/> Information Disclosure Statements (PTO-1449 or PTO/SB/08),<br/>Paper No./Mail Date _____</li> <li>4. <input type="checkbox"/> Examiner's Comment Regarding Requirement for Deposit<br/>of Biological Material</li> </ol> | <ol style="list-style-type: none"> <li>5. <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)</li> <li>6. <input checked="" type="checkbox"/> Interview Summary (PTO-413),<br/>Paper No./Mail Date _____</li> <li>7. <input checked="" type="checkbox"/> Examiner's Amendment/Comment</li> <li>8. <input checked="" type="checkbox"/> Examiner's Statement of Reasons for Allowance</li> <li>9. <input type="checkbox"/> Other _____</li> </ol> |
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### **EXAMINER'S AMENDMENT**

Applicant's amendment filed on 3/11/05 has been entered. Claims 1-18, 22-23, 27-30, and 33-39 are canceled. Claims 19-21, 24-26, and 31-32 are pending in the instant application.

All rejections of previously pending claims 22-23, 27, 29, 33, and 35-39 are rendered moot by the cancellation of the claims.

In view of applicant's amendments to the claims filed on 3/11/05 and the examiner's amendment found below, the rejection of pending claims 19-21, 24-26, and 31-32 under 35 U.S.C. 102(b) as being anticipated by Link et al. (1996) Human Gene Therapy, Vol. 7, 1161-1179, and under 35 U.S.C. 112, first paragraph, for scope of enablement are withdrawn. Please see the reasons for allowance below for a detailed explanation.

An examiner's amendment to the record appears below. Should the changes and/or additions be unacceptable to applicant, an amendment may be filed as provided by 37 CFR 1.312. To ensure consideration of such an amendment, it MUST be submitted no later than the payment of the issue fee.

Authorization for this examiner's amendment was given in a telephone interview with Janae E. Lehman Bell on 5/26/05.

The application has been amended as follows:

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1. Claim 19 has been rewritten as follows:

Claim 19: A method for treating a solid tumor in a human subject, the method comprising:

administering to the subject and at or near the solid tumor an effective amount of xenogeneic retroviral vector producer cells having  $\alpha(1,3)$  galactosyl epitopes to activate a hyperacute rejection response, wherein administration of said vector producer cells is not followed by treatment with ganciclovir.

Following entry of this examiner's amendment, claims 19-21, 24-26, and 31-32 are considered free of the prior art of record and allowed.

The following is an examiner's statement of reasons for allowance. The applicant's amendments to independent claims 19, 26, and 32 added the limitations that the methods were for the treatment of solid tumors and that the method steps comprised the administration at or near a solid tumor of xenogeneic retroviral vector producer cells. Following entry of this amendment, the currently pending claims 19-21, 24-26, and 31-32 meet the acknowledged scope of enablement discussed in detail in the previous office action. As such, the rejection of the pending claims under 35 U.S.C. 112, first paragraph, has been withdrawn. Following entry of the examiner's amendment, independent claims 19, 26, and 32 recite methods which now include the limitation that the administration of the vector producer cells is not followed by treatment with ganciclovir. While the applicant has stated that support for this negative limitation can be found within pages 13, 15-17, and 19 of the specification, the office finds support for this limitation

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primarily on pages 13-14, bridging sentence, which states that, "The present invention is able to create antitumor responses without the need for gene transfection and the addition of a prodrug". Note that the working examples all list ganciclovir as a prodrug. The addition of this limitation to the claims has resulted in the withdrawal of the rejection under 35 U.S.C. 102(b) over Link et al. Link et al. does not contemplate or suggest a method of treating a solid tumor where the administration of xenogeneic retroviral vector producer cells is not followed by the administration of the prodrug ganciclovir.

Any comments considered necessary by applicant must be submitted no later than the payment of the issue fee and, to avoid processing delays, should preferably accompany the issue fee. Such submissions should be clearly labeled "Comments on Statement of Reasons for Allowance."

Any inquiry concerning this communication from the examiner should be directed to Anne Marie S. Wehbé, Ph.D., whose telephone number is (571) 272-0737. The examiner can be reached Monday- Friday from 9:30-6:00 EST. If the examiner is not available, the examiner's supervisor, Ram Shukla, can be reached at (571) 272-0735. For all official communications, **the new technology center fax number is (571) 273-8300**. For informal, non-official communications only, the examiner's direct fax number is (571) 273-0737.

Dr. A.M.S. Wehbé

ANNE M. WEHBE' PH.D  
PRIMARY EXAMINER

